

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhongshan Siyuan Electric Co., LTD

Model Tested: k003-2

Date Tested: August 3, 2020

These findings pertain to the Zhongshan Siyuan Electric Co., LTD, Model k003-2. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator). The packaging for this product indicates that it also meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#).

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 86.30% and 55.60%, respectively. All respirators measured less than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for [Crisis Capacity Strategies \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: August 3, 2020

Report Prepared: August 3, 2020

Manufacturer: Zhongshan Siyuan Electric Co., LTD

Item Tested: k003-2

Country of Certification: China (GB2626-2006), European (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

| Filter | Flow Rate (LPM) | Initial Filter Resistance (mmH ₂ O) | Initial Percent Leakage (%) | Maximum Percent Leakage (%) | Filter Efficiency (%) |
|--|-----------------|--|--|-----------------------------|-----------------------|
| 1 | 85 | 6.6 | 36.7 | 36.7 | 63.30 |
| 2 | 85 | 6.6 | 38.5 | 38.5 | 61.50 |
| 3 | 85 | 5.2 | 44.4 | 44.4 | 55.60 |
| 4 | 85 | 6.4 | 38.2 | 38.2 | 61.80 |
| 5 | 85 | 6.7 | 41.6 | 41.6 | 58.40 |
| 6 | 85 | 4.8 | 43.3 | 43.3 | 56.70 |
| 7 | 85 | 6.3 | 35.7 | 35.7 | 64.30 |
| 8 | 85 | 6.3 | 17.7 | 17.7 | 82.30 |
| 9 | 85 | 5.9 | 43.9 | 43.9 | 56.10 |
| 10 | 85 | 6.4 | 13.7 | 13.7 | 86.30 |
| Minimum Filter Efficiency: 55.60% | | | Maximum Filter Efficiency: 86.30% | | |

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.

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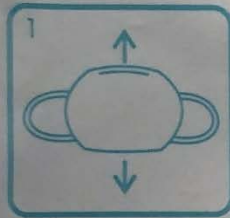




MASK

DISPOSABLE PROTECTIVE

Instructions :



Stretch unfolded mask.



Wear rubber bands on both sides.



Press the bridge of the nose and sides to make it more conformable.

Precautions :

1. It is not recommended to use this product under the condition of low oxygen, heavy air pollution, poor breathing or during sleep.
2. For patients with severe asthma or other severe respiratory diseases, please use with caution.
3. Please use the masks properly. Do not modify or misuse it at will to avoid serious consequences caused by improper usage.
4. Store in an environment with the temperature of -20°C to 38°C and the relative humidity of the environment shall be lower than 80%.

FDA CE
MADE IN CHINA

合格证



产品名称：环保舒适型防护口罩

型号：k003-2

生产日期：见包装袋

检查员：QC02

保质期：有效期5年

执行标准：GB 2626-2006 KN95

EN149:2001+A1:2009 FFP2

制造商：中山市思源电器有限公司

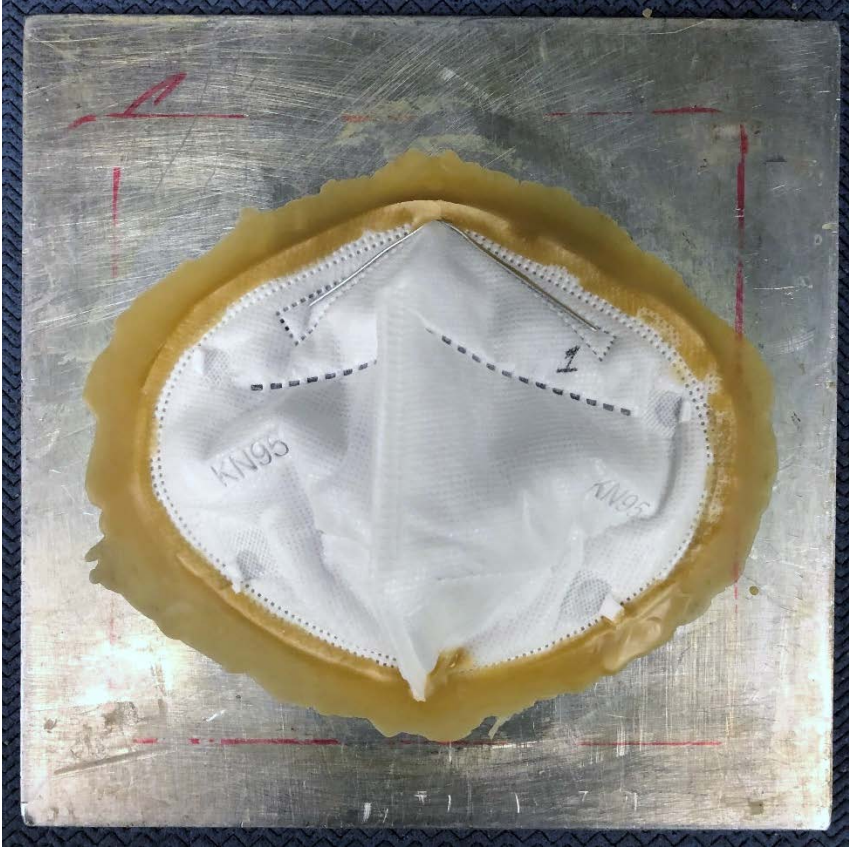
生产地址：中山市南头镇尚俭路28号



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